U.S. Food and Drug Administration

JOINT SUMMARY OF THE MEETING OF THE JOINT SECTORAL COMMITTEE OF THE PHARMACEUTICAL GOOD MANUFACTURING PRACTICE ANNEX OF THE U.S.-EC MUTUAL RECOGNITION AGREEMENT

18-19 MAY 1999

The Joint Sectoral Committee (JSC) responsible for monitoring the implementation of the Pharmaceutical Annex of the EC-US Mutual Recognition Agreement (MRA) met in plenary session for the first time on 18 and 19 May, 1999 in the headquarters offices of the U.S. Food and Drug Administration (FDA) in Rockville, Maryland. During this meeting, representatives of the FDA, the European Commission (Directorate General III), the European Agency for the Evaluation of Medicinal Products (EMEA), and representatives of EU Member State regulatory authorities discussed current and upcoming issues related to the implementation of the Annex. The discussions included Terms of Reference for the JSC, ways to facilitate regular communications between FDA, the EMEA, and other EC regulatory authorities, confidentiality issues, the elements of a two-way alert system, and an overview of general working programs and draft equivalence assessment programs.

To facilitate implementation of the Annex, Terms of Reference were drafted that describe the roles, responsibilities, and procedures of the JSC. Particular emphasis was placed on responsibilities involving coordination, monitoring and communication between the parties to the agreement. It was agreed to designate contacts that would serve as focal points for information exchanges. The timely exchange of information would help to ensure consistency and transparency in making equivalence determinations.

Due to different requirements for the disclosure of information in the U.S. and the EU, the discussion on confidentiality issues outlined the need for a working approach in handling documents that contain non-public information. This topic will be further explored jointly so an exchange of information can be maintained during the implementation process.

The parameters and objectives for establishing a two-way alert system were discussed and preliminary identification of the types of information that could be exchanged was made. A joint working group will be formed to develop the essential elements of a two-way alert system to protect public health.

The parties shared their draft general working and equivalence assessment programmes, outlining their methodologies for assessing equivalence. There was a discussion about whether FDA would be able to complete equivalence assessments for all Member States within the three year transitional period.

The parties were pleased with the progress achieved at this meeting and agreed to have monthly contacts of the JSC Co-Chairs to discuss implementation progress.

The text of the MRA Sectoral Annex for Pharmaceutical Good Manufacturing Practices can be found at: http://www.fda.gov and http://europa.eu.int/en/comm/dg01/mra03.htm. This statement, together with other information on the EMEA, may be found at http://www.eudra.org/emea.html.

(Hypertext by mev May 20, 1999)